

# Notice of Allowability

Application No.

10/718,693

Examiner

Gary W. Counts

Applicant(s)

EBESU ET AL.

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## -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to communication filed 06/28/05.
2. ☒ The allowed claim(s) is/are 21-26 and 36 (renumbered 1-7 respectively).
3. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
  - a) ☐ All b) ☐ Some\* c) ☐ None of the:
    1. ☐ Certified copies of the priority documents have been received.
    2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
    3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

\* Certified copies not received: \_\_\_\_\_.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.

**THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.**

4. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
5. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
  - (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
    - 1) ☐ hereto or 2) ☐ to Paper No./Mail Date \_\_\_\_\_.
  - (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date \_\_\_\_\_.

Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).
6. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

### Attachment(s)

1. ☒ Notice of References Cited (PTO-892)
2. ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3. ☒ Information Disclosure Statements (PTO-1449 or PTO/SB/08), Paper No./Mail Date 01/28/04
4. ☐ Examiner's Comment Regarding Requirement for Deposit of Biological Material
5. ☐ Notice of Informal Patent Application (PTO-152)
6. ☒ Interview Summary (PTO-413), Paper No./Mail Date 09/15/05
7. ☒ Examiner's Amendment/Comment
8. ☒ Examiner's Statement of Reasons for Allowance
9. ☐ Other \_\_\_\_\_

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### **EXAMINER'S AMENDMENT**

1. An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it **MUST** be submitted no later than the payment of the issue fee.

Authorization for this examiner's amendment was given in a telephone interview with Meera Narasimhan, Attorney on September 14, 2005.

#### **IN THE SPECIFICATION:**

On page 1 after the disclosure "a division of Application Serial No. 09/901,016 filed July 10, 2001," insert -- now U.S. Pat. No. 6,652,807, - -.

#### **IN THE CLAIMS:**

Cancel claims 27-35 without prejudice.

Claim 21 has been replaced as follows:

Claim 21 Method of detecting toxins in a tissue sample comprising:

(a) providing a housing having a main chamber for receiving the tissue sample, first and second end chambers having areas smaller than an area of the main chamber and communicating with opposite ends of the main chamber, wherein the first chamber comprises a coring tube and wherein the second end chamber comprises an assay chamber for analysis of extracted sample,

(b) collecting a tissue sample with the coring tube,

(c) coupling a reagent cap comprising reagent with the first end chamber and squeezing the reagent cap to supply the reagent and to position the tissue sample in the main chamber,

(d) incubating the reagent and tissue sample in the main chamber to form a solution,

(e) supplying the formed solution from the main chamber into the assay chamber,

(f) generating and detecting assay signals from the assay chamber, and

(g) detecting the toxins in the tissue sample.

Claim 22, line 3 delete the recitation "tube" and replace with --chamber--.

Claim 22, line 4 delete the recitation "substances" and replace with --toxins--.

Claim 24, line 2 delete the recitation "an antibodies" and replace with --antibodies--.

Claim 24, line 2 delete the recitation "an analyte" and replace with --the toxins--.

Claim 25 has been replaced as follows:

Claim 25 The method of claim 21, further comprising after step (d) removing the reagent cap and replacing with a second reagent cap, wherein the second reagent cap comprises labeled antibodies specific to the toxin, and squeezing the second reagent cap to supply the labeled antibodies to the solution.

Claim 26, line 2 after the recitation "comparing" insert --the analyzed signals--.

Claim 26, line 3 after the recitation "determining" insert --the--.

Added claim 36 as follows:

Claim 36 The method of claim 25 wherein the detection of the signals is performed by Raman Spectroscopy.

***Allowable Subject Matter***

2. The following is an examiner's statement of reasons for allowance: The prior art neither teaches nor suggests a method for detecting toxins in a tissue sample comprising a housing as recited and collecting a sample with a corer and coupling a reagent cap to the corer comprising squeezing the reagent cap to supply the reagent and performing detection steps to determine the toxin.

Hokama (US 4,816,392), Hood et al (US 5,919,356) and Nason et al (US 5,869,003) are considered to be the closest prior art.

Hokama disclose collecting a tissue sample and detecting for toxins. Hokama does not teach nor suggest a method as instantly claimed.

Hood et al disclose an apparatus comprising a housing (12) that comprises a main chamber comprising a filtration means. Hood et al disclose a first end chamber comprised of a needle (5) and female luer lock (4) and male luer lock 4'. Hood et al disclose a collection chamber (second end chamber) that comprises a sensing means (21). Hood et al disclose a cap coupled with the first end chamber (see figures 7 and 8). Hood et al also disclose that the sensing means can be detected spectrophotometrically (col 4, lines 23-30). Hood et al disclose that the needle can be a biopsy needle or small bore needle (col 6, lines 54-67). Hood et al disclose that the sample can be a fish sample (col 1, lines 60-65). Hood does not teach nor suggest a

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squeezable reagent cap to supply the reagent and to position the tissue sample in the main chamber,

Nason et al disclose an apparatus comprising a plurality of tubes (figure 15) forming a main chamber for receiving a sample, first and second end chambers on opposite ends of the main chamber. Nason et al disclose a removable reagent cap (figure 16) for expressing on the sample in the chambers. Nason et al disclose assay in the second end chamber (col 6, lines 14-34 and figure 16). Nason et al disclose an open-end for collecting the sample. Nason et al does not teach an analyzer or detector for receiving data from the assay and analyzing substances in the tissue sample for detecting toxins or the first and second end chambers having areas smaller than an area in the main chamber and communicating with opposite ends of the main chamber. Nor does Nason teach the first end chamber forming an open-ended tissue coring tube, wherein the tissue coring tube is beveled to facilitate sample collection.

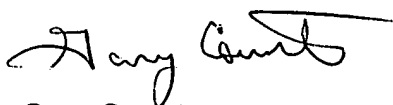
Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Gary W. Counts whose telephone number is (571) 2720817. The examiner can normally be reached on M-F 8:00 - 4:30.

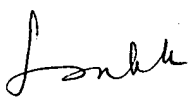
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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached on (571) 272-0823. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Gary Counts  
Examiner  
Art Unit 1641  
September 15, 2005



LONG V. LE  
SUPERVISORY PATENT EXAMINER  
TECHNOLOGY CENTER 1600  
09/18/05